IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

DOLLY ALLEN,

Plaintiff,

v. **Civil Action No. 2:13-cv-06738**

BOSTON SCIENTIFIC CORP.,

Defendant.

MEMORANDUM OPINION AND ORDER
(Defendant's Motion for Summary Judgment)

Pending before the court is Boston Scientific Corp.'s ("BSC") Motion for Summary Judgment Against Plaintiff Dolly Allen ("Motion") [Docket 52]. As set forth below, BSC's Motion is **GRANTED IN PART** with respect to the plaintiff's claims of strict liability for manufacturing defect, negligent manufacturing, and breaches of express and implied warranties. BSC's Motion is **DENIED IN PART** with respect to the plaintiff's claims of strict liability for design defect, strict liability for failure to warn, negligent design, and negligent failure to warn.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 72,000 cases currently pending, approximately 19,000 of which are in the Boston Scientific Corp. MDL, MDL 2326. In an effort to efficiently and effectively manage this massive MDL, I decided to conduct pretrial discovery and motions practice on an individualized basis so that once a case

is trial-ready, it can then be promptly transferred or remanded to the appropriate district for trial. To this end, I ordered the plaintiffs and defendant to each select 50 cases, which would then become part of a "wave" of cases to be prepared for trial and, if necessary, remanded. (*See* Pretrial Order # 65, *In re Boston Scientific Corp. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-002326, entered Dec. 19, 2013, *available at* http://www.wvsd.uscourts.gov/MDL/boston/orders.html). This selection process was completed twice, creating two waves of 100 cases, Wave 1 and Wave 2. Ms. Allen's case was selected as a Wave 2 case by the plaintiffs.

Ms. Allen was surgically implanted with the Obtryx Transobturator Mid-Urethral Sling System (the "Obtryx") on November 9, 2007. (Short Form Compl. [Docket 1] ¶¶ 8, 10). She received the surgery at a hospital in Easton, Maryland. (*Id.* ¶ 11). Her implanting surgeon was Dr. Edmond J. Fitzgerald. (*Id.* ¶ 12). Ms. Allen claims that as a result of implantation of the Obtryx, she has experienced multiple complications, including urinary problems after transvaginal implant, dyspareunia, infection, stress urinary incontinence, corrective surgery, cysts, pain in low back, pain in bladder area, emotional stress, and bleeding. (Second Supplemental Answers to Pl. Fact Sheet, Ex. B [Docket 52-1], at 8). She brings the following claims against BSC: strict liability for manufacturing defect, design defect, and failure to warn; negligence; breaches of express and implied warranties; and punitive damages. (Short Form Compl. [Docket 1] ¶ 13).

II. Legal Standards

A. Summary Judgment

To obtain summary judgment, the moving party must show that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). In considering a motion for summary judgment, the court will not "weigh the evidence and determine the truth of the matter." *Anderson v. Liberty Lobby, Inc.*, 249 (1986). Instead, the court will draw any permissible inference from the underlying facts in the light most

favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587–88 (1986).

Although the court will view all underlying facts and inferences in the light most favorable to the nonmoving party, the nonmoving party nonetheless must offer some "concrete evidence from which a reasonable juror could return a verdict" in his or her favor. *Anderson*, 477 U.S. at 256. Summary judgment is appropriate when the nonmoving party has the burden of proof on an essential element of his or her case and does not make, after adequate time for discovery, a showing sufficient to establish that element. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). The nonmoving party must satisfy this burden of proof by offering more than a mere "scintilla of evidence" in support of his or her position. *Anderson*, 477 U.S. at 252. Likewise, conclusory allegations or unsupported speculation, without more, are insufficient to preclude the granting of a summary judgment motion. *See Dash v. Mayweather*, 731 F.3d 303, 311 (4th Cir. 2013); *Stone v. Liberty Mut. Ins. Co.*, 105 F.3d 188, 191 (4th Cir. 1997).

B. Choice of Law

Under 28 U.S.C. § 1407, this court has authority to rule on pretrial motions in MDL cases. The choice of law for these pretrial motions depends on whether they concern federal or state law:

> When analyzing questions of federal law, the transferee court should apply the law of the circuit in which it is located. When considering questions of state law, however, the transferee court must apply the state law that would have applied to the individual cases had they not been transferred for consolidation.

In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig., 97 F.3d 1050, 1055 (8th Cir. 1996) (internal citations omitted). To determine the applicable state law for a dispositive motion, I generally refer to the choice-of-law rules of the jurisdiction where the plaintiff first filed her claim. *See In re Air Disaster at Ramstein Air Base, Ger.*, 81 F.3d 570, 576 (5th Cir. 1996) ("Where a transferee court presides over several diversity actions consolidated under the multidistrict rules,

the choice of law rules of each jurisdiction in which the transferred actions were originally filed must be applied."); *In re Air Crash Disaster Near Chi., Ill.*, 644 F.2d 594, 610 (7th Cir. 1981); *In re Digitek Prods. Liab. Litig.*, MDL No. 2:08-md-01968, 2010 WL 2102330, at *7 (S.D. W. Va. May 25, 2010).

If a plaintiff files her claim directly into the MDL in the Southern District of West Virginia, however, as Ms. Allen did in this case, I consult the choice-of-law rules of the state in which the plaintiff was implanted with the product. *See Sanchez v. Boston Scientific Corp.*, 2:12-cv-05762, 2014 WL 202787, at *4 (S.D. W. Va. Jan. 17, 2014) ("For cases that originate elsewhere and are directly filed into the MDL, I will follow the better-reasoned authority that applies the choice-of-law rules of the originating jurisdiction, which in our case is the state in which the plaintiff was implanted with the product."). Ms. Allen received her implantation surgery in Maryland. (Short Form Compl. [Docket 1], ¶ 11). Thus, the choice-of-law principles of Maryland guide this court's choice-of-law analysis.

These principles compel application of Maryland law to the plaintiff's claims. In tort actions, Maryland "adheres to the *lex loci delicti* rule in analyzing choice of law problems." *Philip Morris Inc. v. Angeletti*, 752 A.2d 200, 230 (Md. 2000). Under this rule, a court must apply "the law of the state in which the alleged tort took place." *Lab. Corp. of Am. v. Hood*, 911 A.2d 841, 844 (Md. 2006). Here, the implantation surgery that allegedly resulted in Ms. Allen's injuries took place in Maryland. (*See* Short Form Compl. [Docket 1] ¶¶ 11, 13). Thus, I apply Maryland's substantive law to this case.

III. Analysis

A. Strict Liability

Maryland has adopted the doctrine of strict liability under section 402A of the Restatement (Second) of Torts ("Restatement"). *See Phipps v. Gen. Motors Corp.*, 363 A.2d 955, 963 (Md. 1976). Section 402A provides:

> (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
>
> (a) the seller is engaged in the business of selling such a product, and
> (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
>
> (2) The rule stated in Subsection (1) applies although
>
> (a) the seller has exercised all possible care in the preparation and sale of his product, and
> (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

Restatement § 402A.

To prevail on a strict liability claim, the plaintiff must establish that (1) the product was in a defective condition at the time that it left the possession or control of the seller, (2) the product was unreasonably dangerous to the user or consumer, (3) the defect was a cause of the injuries, and (4) the product was expected to and did reach the consumer without substantial change in its condition. *Phipps*, 363 A.2d at 958. For purposes of strict products liability, a product may be defective in one of three ways: (1) a flaw exists in the product at the time the defendant sold it, making the product more dangerous than was intended, (2) a producer of a product fails to warn adequately of a risk or hazard related to the way a product was designed, or (3) a product is defectively designed. *Simpson v. Standard Container Co.*, 527 A.2d 1337, 1339–40 (Md. Ct. Spec. App. 1987).

1. Manufacturing Defect

The plaintiff concedes the claim of strict liability for manufacturing defect. (Pl.'s Resp. to Def.'s Mot. for Summ. J. ("Resp.") [Docket 65], at 9). Therefore, BSC's Motion on the plaintiff's claim of strict liability for manufacturing defect is **GRANTED**.

2. Design Defect

To recover for design defect, "the plaintiff must prove that the product was in a defective condition *and* unreasonably dangerous at the time the product was sold." *Ziegler v. Kawasaki Heavy Indus., Ltd.*, 539 A.2d 701, 704 (Md. Ct. Spec. App. 1988) (emphasis in original). The critical question in a design defect claim is "whether a manufacturer, knowing of the risks inherent in his product, acted reasonably in putting it on the market." *Id.* at 705 (quoting *Singleton v. Int'l Harvester Co.*, 685 F.2d 112, 115 (4th Cir. 1981)). This question "depends on 'the balancing of the utility of the design and other factors against the magnitude of that risk.'" *Id.* (quoting *Phipps*, 363 A.2d at 961). If the utility of the design outweighs the risks, then the product is not unreasonably dangerous. *See id.* Alternatively, if a product is unavoidably unsafe, then it is not unreasonably dangerous. *Doe v. Miles Labs., Inc., Cutter Labs. Div.*, 927 F.2d 187, 190 (4th Cir. 1991).

Comment k of section 402A of the Restatement describes certain products as "unavoidably unsafe products." Courts have universally interpreted this term to encompass prescription pharmaceuticals, whether categorically or for particular prescription pharmaceuticals, and the vast majority of courts that have considered the issue have found that the category of "unavoidably unsafe products" can also apply to prescription medical devices. I see no persuasive reason why comment k should not be capable of applying to mesh devices such as the Obtryx.

Courts have varied in their treatment of comment k. Some courts have found that comment k categorically bars design defect for certain medical products. *See, e.g.*, *Brown v. Superior Court*, 751 P.2d 470, 477 (Cal. 1988) (leading case adopting categorical approach). Thus, in these states,

comment k is an absolute bar to claims of design defect for particular classes of products. Other courts have adopted a case-by-case approach. *See, e.g.*, *Toner v. Lederle Labs., a Div. of Am. Cyanamid Co.*, 732 P.2d 297, 308 (Idaho 1987) (leading extant case adopting case-by-case approach). Thus, in these states, whether comment k bars a claim of design defect depends on the particular product at hand.

Maryland follows the case-by-case approach. The application of comment k is a mixed question of law and fact. *Kearl v. Lederle Labs.*, 218 Cal. Rptr. 453, 463 (Ct. App. 1985), *disapproved of on other grounds by Brown v. Superior Court*, 751 P.2d 470 (Cal. 1988). Determining whether comment k applies "require[s] a full evidentiary hearing." *Toner*, 732 P.2d at 308; *see Lundgren v. Ferno-Washington Co.*, 565 A.2d 335, 338 (Md. Ct. Spec. App. 1989). A matter that requires a full evidentiary hearing cannot be resolved at the summary judgment stage. Therefore, BSC's Motion on the plaintiff's claim of strict liability for design defect is **DENIED**.

3. Failure to Warn

Maryland courts recognize the learned intermediary doctrine. *See Nolan v. Dillon*, 276 A.2d 36, 40 (Md. 1971) (applying doctrine to pharmaceuticals); *Hunt ex rel. Hunt v. Hoffmann–La Roche, Inc.*, 785 F. Supp. 547 (D. Md. 1992) (same). Under the learned intermediary doctrine, the manufacturer of medical devices need not warn a patient of the risks associated with a product used under the supervision of a doctor. *See Lee v. Baxter Healthcare Corp.*, 721 F. Supp. 89, 94–95 (D. Md. 1989), *aff'd sub nom. Lee v. Baxter Health Care Corp.*, 898 F.2d 146 (4th Cir. 1990) (unpublished table opinion); *Miller v. Bristol-Myers Squibb Co.*, 121 F. Supp. 2d 831, 838 (D. Md. 2000). Rather, it need only warn the doctor, the learned intermediary, who is in the "best position to understand the patient's needs and assess the risks and benefits of a particular course of treatment." *Lee*, 721 F. Supp. at 95. Federal courts applying Maryland law have extended the

learned intermediary doctrine to medical devices. *See, e.g.*, *id.* at 94–95; *Miller*, 121 F. Supp. 2d at 838.

In addition, to be "legally adequate," a warning is required to "explain[] the risk which the plaintiff alleges has caused the injury." *Lee*, 721 F. Supp. at 95. Maryland law does not require the best of all possible warnings, only a reasonable warning. *Nolan v. Dillon*, 276 A.2d 36, 40 (Md. 1971). However, "[e]ven if a label's warnings are inadequate, the doctrine protects a manufacturer from liability provided the doctor has been sufficiently warned from other sources." *Ames v. Apothecon, Inc.*, 431 F. Supp. 2d 566, 572 (D. Md. 2006).

In the context of the learned intermediary doctrine, a learned intermediary relies not only on a manufacturer's warnings, but also on his or her own skill, judgment, and experience in determining whether to use a medical product. Thus, any warning read by the physician "means only that the learned intermediary would have incorporated the additional risk into his decisional calculus." *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 814 (5th Cir. 1992) (internal quotation marks omitted) (distinguishing preventable-risk warnings and unavoidable-risk warnings); *accord Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003 (4th Cir. 1992); *Eck v. Parke, Davis & Co.*, 256 F.3d 1013, 1021 (10th Cir. 2001). The plaintiff would still need to show that "the additional non-disclosed risk was sufficiently high that it would have changed the treating physician's decision to prescribe the product." *Thomas*, 949 F.2d at 814; *accord Willett v. Baxter Int'l, Inc.*, 929 F.2d 1094, 1098–99 (5th Cir. 1991); *Thom v. Bristol-Myers Squibb Co.*, 353 F.3d 848, 856 (10th Cir. 2003); *Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 997 (C.D. Cal. 2001) *aff'd sub nom. Motus v. Pfizer Inc. (Roerig Div.)*, 358 F.3d 659 (9th Cir. 2004); *Harris v. Purdue Pharma, L.P.*, 218 F.R.D. 590, 596 (S.D. Ohio 2003); *see Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652, 660 (1st Cir. 1981); *Van Buskirk v. Carey Canadian Mines, Ltd.*, 760 F.2d 481, 492–93 (3d Cir. 1985); *Menges v. Depuy*

Motech, Inc., 61 F. Supp. 2d 817, 830 (N.D. Ind. 1999); *Mazur v. Merck & Co.*, 742 F. Supp. 239, 262 (E.D. Pa. 1990).

Here, the plaintiff has offered concrete evidence from which a reasonable juror could return a verdict in her favor, and genuine disputes of material fact exist with regard to (1) whether BSC's warning was adequate, and (2) whether the alleged inadequate warning proximately caused the alleged harm to the plaintiff. Therefore, BSC's Motion on the plaintiff's claim of strict liability for failure to warn is **DENIED**.

B. Negligence

"The negligence count of a products liability claim comports with longstanding common law tort principles." *Nissen Corp. v. Miller*, 594 A.2d 564, 567 (Md. 1991). The injured party must show "(1) that the defendant was under a duty to protect the plaintiff from injury, (2) that the defendant breached that duty, (3) that the plaintiff suffered actual injury or loss, and (4) that the loss or injury proximately resulted from the defendant's breach of the duty." *Doe v. Pharmacia & Upjohn Co.*, 879 A.2d 1088, 1092 (Md. 2005); *accord Dehn v. Edgecombe*, 865 A.2d 603, 611 (Md. 2005); *Horridge v. St. Mary's Cnty. Dep't of Soc. Servs.*, 854 A.2d 1232, 1238 (Md. 2004); *Patton v. USA Rugby*, 851 A.2d 566, 570 (Md. 2004).

Here, the plaintiff's negligence claims fall into the same three categories as their strict liability claims: (1) negligent manufacturing, (2) negligent failure to warn, and (3) negligent design. (*See* Master Long Form Compl. & Jury Demand, MDL No. 2326, ¶¶ 55–59; Short Form Compl. [Docket 1] ¶ 13). BSC has moved for summary judgment on each category.

1. Negligent Manufacturing

The plaintiff concedes the claim of negligent manufacturing. (Resp. [Docket 65], at 9). Therefore, BSC's Motion on the plaintiff's claim of negligent manufacturing is **GRANTED**.

2. Negligent Design

BSC has presented no argument on negligent design other than its argument regarding comment k. *See supra* Part III.A.2. Therefore, BSC's Motion on the plaintiff's claim of negligent design is **DENIED**.

3. Negligent Failure to Warn

Negligence claims based on a failure to warn are nearly identical to strict liability claims based on a failure to warn. *See Owens-Illinois, Inc. v. Zenobia*, 601 A.2d 633, 640 n.7 (Md. 1992) (noting the "overlap of negligence principles in a strict liability failure to warn case").

As explained earlier, genuine disputes of material fact exist with regard to (1) whether BSC's warning was adequate, and (2) whether the alleged inadequate warning proximately caused the alleged harm to the plaintiff. *See supra* Part III.A.3. Therefore, BSC's Motion on the plaintiff's claim of negligent failure to warn is **DENIED**.

C. Breaches of Express and Implied Warranties

I earlier held that the plaintiff's warranty claims are time barred by the statute of limitations. (Mem. Op. & Order [Docket 97], at 8, 2015 WL 1133518 at *5). Therefore, BSC's Motion on the plaintiff's claims of breaches of express and implied warranties is **GRANTED**.

IV. Conclusion

For the reasons discussed above, it is **ORDERED** that BSC's Motion [Docket 52] be **GRANTED IN PART** with respect to the plaintiff's claims of strict liability for manufacturing defect, negligent manufacturing, and breaches of express and implied warranties, and **DENIED IN PART** with respect to the plaintiff's claims of strict liability for design defect, strict liability for failure to warn, negligent design, and negligent failure to warn.

The Court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: October 5, 2015

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE